

§Appl. No. 09/971,708
Amdt. dated October 21, 2003
Reply to Office Action of, July 25, 2003

REMARKS

Rejections under §101 and §112, first paragraph

As indicated in the specification, KSE132 is a tyrosine kinase. See, e.g., Specification, Page 2, lines 15-20. Tyrosine kinase activity can be measured routinely, e.g., as described on Page 4, line 10-Page 5, line 11 of the specification. For example, KSE132 can be used to label substrates with radioactive phosphorus for use in assays.

Enzyme activity is adequate to satisfy the utility requirements. See, e.g., *Revised Interim Utility Guideline Training Materials*, Example 8, Page 45, under section titled "Analysis," subheading "1)." Consistently, the Federal Circuit in *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), held that an *in vitro* pharmacological activity for thromboxane synthetase (an enzyme) was sufficient to satisfy the requirements of 35 U.S.C. §101. See, also, M.P.E.P. 2107.01. Thus, knowledge that KSE132 is a tyrosine kinase is a credible, specific, and substantial utility.

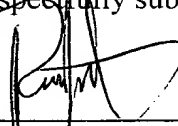
Moreover, KSE132 is highly restricted to the brain, pancreas, and testis. See, Specification, Fig. 1, and Page 2, lines 26-31. The other cell types in which it is expressed (i.e., brain and testis) do not detract from its utility as a tissue marker, e.g., as a pancreas marker. For instance, in a patient with pancreatic cancer, it can be used to detect metastatic pancreatic cells, e.g., when metastasis from a primary pancreatic tumor site has occurred, or in a biopsy of the pancreas to identify the pancreatic tissue. See, e.g., Specification, Page 33, lines 1-10; Page 24, beginning on line 29.

In view of these comments, withdrawal of the rejection is respectfully requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

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The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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